Please add the following claims.

38. The combination of claim 30 wherein full deployment of said detachable elongate tip portion in said body cavity by said predetermined distance positions a coupling of said detachable elongate tip portion to said wire approximately 2 - 3 mm past said opening of said body cavity.

39. The combination of claim 30 wherein said detachable elongate tip portion is a long and substantially pliable segment adapted to be multiply folded upon itself to substantially pack body cavity.

40. The combination of claim 30 wherein said detachable elongate tip portion is 4-40 cm in length.

41. The combination of claim 30 wherein said wire and detachable elongate top portion are coupled by polyester.

42. The combination of claim 30 wherein said tip portion is detachable from said core wire by electrolytic disintegration of part of said wire.

Remarks

Claims 1 - 24 were original in the application and have been canceled without prejudice. Claims 25 - 37 were added as better defining the invention.

Claims 25 – 29 and 35 have been cancelled. Claims 30 and 31 have been amended to stand in independent form with claims 32 – 34, 36 and 37 directly or indirectly dependent thereon. Claims 38 – 42 have been added to provide a parallel dependent claim chain to both claims 30 and 31.

The Examiner has objected to claim 33 under 35 USC 112, which in each case has been responsively amended with thanks for the review provided.

Rejection Under 35 USC 103(a)

Claim 25 has be rejected as obvious over **Anderson et.al.** *"Transcatheter Intravascular Coil Occlusion of Experimental Arteriouvenous Fistulas,"* Am. J. Rentgenol. 129: 795-798, (1977) in view of **Geremia et.al.**, *"Method and Apparatus for Placement of an Embolic Coil,"* U.S. Patent 5,108,407 (1992). **Anderson** shows a tip which is detachable by unscrewing a mechanical coupling and **Geremia** discusses at col. 5, line 64 – col. 6, line 2, the use of a terminal connector 30 of radioopaque material so that placement of an embolic coil in an aneurysm can be detected. Claim 25 has been cancelled, but the references are relevant to the rejection of claims 25 – 34 discussed below.

Claims 25 – 34 were rejected as obvious over **Anderson** in view of **Sullivan**, " *Method for Placement of a Balloon Dilatation Catheter Across a Stenosis and Apparatus Therefor,"* U.S. Patent 5, 209, 730 (1993). **Sullivan** was not characterized in any particular, but is acknowledged to show a wire 18 provided with a plurality of longitudinally spaced radioopaque markers 56. Wire

18 is disposed in a balloon dilation catheter having an inner tube 22 and a balloon marker 43.

Sullivan's wire 18 is disposed through a stenosis while a dye is injected through the stenosis to mark its relative position to wire 18 are revealed by markers 56. See col. 4, lines 61 – 68. Meanwhile, the distal tip of the balloon catheter is maintained some distance away from the stenosis. The physician marks the position of the stenosis relative to the markers 56 on wire 18 by counting markers 56 back from the distal most one to the position of the stenosis. See col. 5, lines 1 –7. Wire 18 is then held stationery and balloon 16 advanced to the recorded position of the stenosis as determined by the alignment of marker 43 on balloon 16 with the recorded one of markers 56 on wire 18. The balloon is locked into place, inflated, the stenosis dilated, the balloon deflated and then withdrawn. The process may be repeated with subsequent balloons substituted onto wire 18. Multiple markers 56 on wire 18 denote the length of balloon 16. See col. 6, lines 34 – 46.

Sullivan teaches the placement of a wire to properly position a balloon along the length of the wire relative to a bodily structure through which wire 18 must completely traverse in order to be operable. In **Geremia** connector 30 is placed near or in the opening to a body cavity to determine when the embolic coil is disposed in the cavity. **Geremia** does not disclose delivery of the coil to the body cavity through a catheter. It is assumed in **Geremia** that the coil has sufficient stiffness to be steerable in some manner into the body cavity.

Where as here the coil is substantially pliant and floppy, **Geremia's** delivery scheme become inoperable inasmuch as there is no means to delivery the floppy coil into the cavity except by remote chance. Instead, it is the experience of applicant that the coil, when freed from the end of the catheter, will if not intimately delivered into the confines of the body cavity simply flow downstream with the blood flow when used in a vascular application. A delivery instrument or catheter is therefor necessary. Therefore, the coil may not be permitted to flap in the blood stream like a flag, but must be confined in the catheter until delivered into the body cavity.

In addition the coil is detachable. Its detachability is dependent on its disposition out of the end of the catheter, whether detachment be by mechanical means or by electrolytic disintegration. The coil is not detachable while inside the catheter, since that would serve no useful end. On the contrary, the coil must be retrievable until detached. Thus, if the original attempt at placement of the coil is not successful or optimal, then the physician must be able to retrieve the coil. Again the coil must be pulled back into the catheter in order to be reliably deliverable to the body cavity on the next placement attempt. Thus, means must be provided to allow the surgeon to know when the coil is either fully retracted into the catheter or fully disposed therefrom. This is not an action which **Sullivan** was required to solve. **Sullivan** in essence put a ruler through the operating theater and then placed a balloon next to the ruler to determine its position. Whether the balloon or any other object was inside, outside or somewhere in between within a delivery catheter or not was not material.

Another problem had to be solved in the invention, which was not considered in the art. Typically, multiple coils need to be disposed in the aneurysm. The coils are radioopaque. The body cavity soon becomes fluoroscopicly opaque after a few coils as a "ball" of multiple coils is created. The next coil to be placed into the "ball" cannot be seen. It is also necessary that no coil ends extend from the opening of the aneurysm to create clotting sites in the vessel. Since the delivery catheter is at or near the opening of the aneurysm, but is too big to be placed into the aneurysm, each coil needs to be detached when it is disposed a predetermined distance away from the tip of the catheter. Again this needs to be repeatedly controllable with each coil placement without actually seeing the coil, since the coil itself disappears into the "ball". Hence, the claimed invention calls for a marker on the wire proximal of the coil-to-wire detachment point to be alignable with a catheter tip marker to indicate coil placement in the "ball" and away from the catheter tip without the need to see the coil.

The Examiner objected to the claims under *In Re Schneller*, 158 USPQ 210 (CCPA 1968) on the ground that there is no apparent reason why applicant was prevented from presenting the claims during an earlier application which has matured into an issued patent.

In Re Schneller was an appeal is from a decision of the Patent Office Board of Appeals affirming the examiner's rejection of claims on the ground of double patenting over an issued copending patent to the same applicant. Unlike

the present case, there was no terminal disclaimer offered in *In Re Schneller.* The CCPA held that:

> "The controlling fact is that patent protection for the clips, fully disclosed in and covered by the claims of the patent, would be extended by allowance of the appealed claims. Under the circumstance of the instant case, wherein we find no valid excuse or mitigating circumstances making it either reasonable or equitable to make an exception, and wherein there is no terminal disclaimer, the rule against "double patenting" must be applied. " 158 USPQ at 214.

The applicant in *In Re Schneller* was attempting to extend the original patent by asserting that the application in question was an independent and distinct invention. This is not the case here, where any extension of U.S.Patent 5,122,136 is expressly disclaimed. Thus, *In Re Schneller* is distinguished from the present application.

A terminal disclaimer over U.S.Patent 5,122,136 is signed and included.

The cross-reference to all prior applications has been added.

The information disclosure statement referenced in the request for filing is being sent under separate cover and includes references which were part of the file history of the immediate parent '795 application.

Advancement of the claims to issuance is respectfully requested.

Respectfully submitted,

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Docket No. M203j-D
Patent

CERTIFICATE OF MAILING

I hereby certify that this Assignment is being deposited in accordance with CFR 37 1.10(a) with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231-3513, on February 1, 1999.

Denise Wyrick
(name of person making deposit)

2-1-99
Date of Signature

Denise Wyrick
Signature